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FACSIMILE TRANSMITTAL SHEET

Date: June 02, 2005 **Total Number of Pages:** 20
(including cover page)

To: Commissioner for Patents
United States Patent & Trademark Office

FAX Number: 01 703 872 9306

From: Martin A Hay

FAX Number: (44) 1625 500058

Acknowledgment Requested: Yes No
Message:

Re: United States Patent No. 6,878,725

Please find attached 19 pages consisting of a Petition for Reconsideration of Patent Term Adjustment and Supporting Documents.

Kindly debit the processing fee of \$400 required under Rule 1.18(f), fee code 1456, to deposit account number 50-1230 (Martin A. Hay & Co)



Hay, Martin Alexander (Reg No. 39,459)

NOTE:

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CERTIFICATION OF FACSIMILE TRANSMISSION	
I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.	
<u>MARTIN A. HAY</u> Type or print name of person signing certification	
<u>[Signature]</u> Signature	<u>June 2, 2005</u> Date

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 6,878,725
Inventors : LIEBESCHUETZ, John Walter, et al.
Assignee : Eli Lilly and Company
Issued : 12 April, 2005
Appln. No. : 10/030,189
Group Art Unit: 1625
Examiner : CHANG, Celia
For : Serine Protease Inhibitors
Docket No. : 00220/US
Customer No. : 024330

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
UNITED STATES

Sir:

PETITION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
AFTER PAYMENT OF ISSUE FEE
(37 C.F.R. § 1.705(d))

Patent No. 6,878,725
Petition under 37 CFR 705(d)

(a) The Issue Notification mailed on March 23, 2005, in the instant application included notification of a patent term adjustment under 35 U.S.C. 154(b) of 0 days.

(b) This is a request for reconsideration of the patent term adjustment indicated in the Issue Notification and is an application for patent term adjustment.

(1) Please charge the requisite fee under 37 C.F.R. § 1.18(f) of \$400.00, and charge any other fee that may be required by this or any other related paper, or credit any overpayment, to Deposit Account No. 50-1230 in the name of Martin A. Hay & Co.

(2) Statement of facts involved:

On October 1, 2003, the undersigned submitted a response to the office action mailed July 1, 2003 under a certificate of fax. The response had been prepared as an electronic document in WORD by the undersigned, starting from the electronic version of the preliminary amendment as filed on national stage entry, and displayed correctly on his computer screen. It was then printed off by the undersigned's assistant. The undersigned then signed the printed response, which appeared to be in order, and completed the certificate of fax. The signed response was submitted by fax. The fax machine generated a printout indicating that 25 pages had been transmitted, as expected. A copy of the printout is attached. It is completely clean, indicating that the fax scanner was working properly.

Although only minor amendments were made in a few of the claims, which would easily have been made under the old procedure for amendment, a complete set of the claims was resubmitted in accordance with the new procedure for use with

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the PTO's new electronic file wrapper process. It may be noted that the amendments were very simple.

After the response was faxed to the PTO, the undersigned continued to monitor the application. The procedures of the undersigned's office require that a diary entry is kept open until responses submitted to the Patent and Trademark Office have been entered into PAIR.

The response was not entered into PAIR for some time, so the undersigned called Customer Service at the Patent and Trademark Office and was reassured that the file had been transferred to docketing on October 1, 2003.

On October 23, 2003, the undersigned wrote to the Eli Lilly and Company, the assignee of the application, and reported that a response had been filed, but that it had not yet been entered into PAIR. A copy of the letter is attached.

On November 6, 2005, the undersigned inspected PAIR and noted that the response had been entered on November 5, 2005 and forwarded to the Examiner. The entry in PAIR was printed off and placed in the undersigned's file. A copy is attached. The diary entry was then closed.

At this point, the undersigned had no idea that anything was wrong with the response as received by the PTO. It had been forwarded to the Examiner.

On December 24, 2003 (Christmas Eve), the undersigned received an office action from the PTO that had been mailed on December 10, 2003. A copy of the front page, showing the date of receipt stamp, is attached. The office action stated that the response filed was illegible, and that a copy was attached. In fact, no copy was attached.

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The same day, December 24, 2003, the undersigned faxed the response once again to the PTO. Again, a diary entry was opened to confirm entry of the response in PAIR. On January 16, 2004, the undersigned noted that the response had been entered on January 15, 2004. The diary entry was closed, and a printout from PAIR was placed on the undersigned's file. A copy is attached.

It is clear from the image in the PTO's electronic file wrapper that the problem with the legibility of the original fax must have been caused by a malfunction of the PTO's fax machine. There are white horizontal bands running down some pages and over markings applied by the PTO. There are also two black circles at the top of each page, suggesting that the pages were first placed on a file, then scanned later. Certainly, the document on the PTO's file is not a facsimile copy of the document originally transmitted to the PTO. The undersigned's facsimile machine could not have been responsible for the black circles or the white horizontal columns.

Irrespective of whether anyone is "to blame" for the malfunction of the technology, it would have been a simple courtesy for the PTO officer processing the fax to call, fax or e-mail the undersigned to inform him that it had not received properly. The response should not have been forwarded to the Examiner until after a clean copy had been received. **This failure of the PTO's technology and failure to promptly contact the undersigned for a fresh copy was the cause of the delay in the allowance of the application.**

In March 2004, the undersigned discovered that the printed response as submitted failed to show the underlinings indicating text in the claims that had been added by amendment. Although the text being added was clear from the

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remarks section in the response, the undersigned judged that the Examiner would appreciate the courtesy of being provided with a copy of the response showing the underlinings. The response was therefore reprinted, and faxed to the PTO on March 10, 2004. A cover sheet was provided, explaining to the Examiner that it was the same response being filed, but with the underlinings now showing. Up until this point in time, the undersigned had been unaware that it was possible for a document to print off on some printers showing the strikethrough lines but not the underlinings.

As fate would have it, the printer used to print off the copy of the response with the underlinings, which was new, also malfunctioned in another respect, and omitted some of the features in some chemical formulae. When this malfunction was discovered, the undersigned had to track down all of the documents that had been printed off using that printer and check the chemical formulae. It was found that one of the formulae in Claim 4 in the reprinted response faxed to the PTO on March 10, 2004 contained errors.

A replacement page 7 of the response, showing the correct formulae, was faxed to the PTO on March 16, 2004, very soon after the error had been discovered. A cover page was included, to explain that no change in the substance of the response was actually being made. Strictly speaking, it should not have been necessary to provide the replacement page, since the Applicants were not amending the formula. However, the undersigned judged that it would be helpful to submit it.

It needs to be noted that the printer error in the formula affected a part of the claims that was not being amended.

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The printer problem has not been solved to this day. The undersigned's staff contacted the manufacturer of the printer, an hp LaserJet 1200, to try to find out why the errors had happened, but they were unable to help. The problem caused huge stress for the undersigned, because the error was not reproducible (the same document printed on the same printer does not always print out with the same errors in the formulae!).

Thus, it is respectfully submitted that the Applicants, through the efforts of the undersigned, did everything that could reasonably be expected to ensure that a complete and accurate document was timely filed for the Examiner in response to the office action of July 1, 2003.

On April 2, 2004, the undersigned received the Notice of Allowance and Determination of Patent Term Adjustment under 35 U.S.C. 154(b). The undersigned assumed that the PTO had correctly determined that the application was not entitled to any patent term adjustment. The Determination of Patent Term Adjustment did not provide any details as to how the patent term adjustment was calculated.

On July 15, 2004, the undersigned paid the issue fee. At the same time, the undersigned also submitted a letter asking the PTO to check that certified copies of the priority documents had been received. He had noted that the Notice of Allowability did not acknowledge that these documents had been received. This letter has been characterized incorrectly in the electronic file history as an amendment after allowance under Rule 312.

The undersigned had actually gone to a great deal of trouble to try to ensure that the certified copies reached the PTO file for the application, even though it is actually the

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PTO's responsibility to do this in a PCT national stage application (See PCT Rule 17.2).

The matter of the certified copies of the priority documents was first drawn to the Examiner's attention in Applicant's response of April 17, 2003. Please see page 4.

The undersigned noted that the Examiner's next office action, mailed July 1, 2003, still did not acknowledge receipt of the priority documents. This was again drawn to the Examiner's attention in the response of October 1, 2003. See page 23. It will be noted from the response that the undersigned actually contacted WIPO to find out what procedure needed to be followed to ensure that the priority documents reached the PTO file.

On April 21, 2004, the undersigned was still concerned that the priority documents had still not been received, so he asked his formalities manager to contact WIPO. Copies of the e-mail communications with the representative at WIPO are attached.

To date, the undersigned has still not received confirmation from the PTO that the certified copies of the priority documents have reached the file.

On March 30, 2005, the undersigned received the Issue Notification for the patent. It indicated that the Patent Term Adjustment was 0 days. This surprised the undersigned, and prompted him to look at PAIR to check how the patent term adjustment had been calculated.

The patent is not subject to any terminal disclaimer.

In conclusion, the undersigned believes that he has done everything that could reasonably be expected to respond to each office action in a timely manner, and to chase up

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whenever PTO communications suggested that any matter remained outstanding. It is therefore respectfully submitted that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704.

On the face of it, Applicants' response of October 1, 2003 placed the application in order for allowance. The Examiner picked up the case for examination on or shortly before December 10, 2003. Someone at the PTO could easily have contacted the undersigned to request resubmission of the response. If the missing underlining had posed a problem for the Examiner (which appears unlikely), then the matter could have readily been dealt with over the telephone. Thus the case should have been allowed around December 10, 2003. The issue fee would have been paid on or before March 10, 2004, and a patent should have issued on or before July 10, 2004, about 10 months before it actually issues. The undersigned calculates that the lost term was 274 days, based upon the assumption that the Examiner should have issued a Notice of Allowance on December 10, 2003.

Disregarding when the Examiner actually picked up the case for examination after the response of October 1, 2003 was filed, a Notice of Allowance should still have been mailed by February 1, 2004, four months after the reply was filed. The reply, had it been received and printed properly by the PTO's fax machine, placed the application in order for acceptance. The Examiner would not have issued a further office action requiring the Applicants to add the underlining, because the amendments made were all clear in the response as filed. Accordingly, if the patent is not entitled to receive the full extension due to the delay prior to issue of the Notice of Allowance, which was term actually lost, then at least the period from when a Notice of Allowance should have been issued

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to when it was actually issued should be restored. This period, calculated in accordance with 37 CFR 1.703(a)(3) is 43 days.

The issue fee was paid on June 15, 2005. Hence the patent should have issued on October 15, 2004. Accordingly, the period from October 15, 2004 until the date of issue should also be restored. This period, calculated in accordance with 37 CFR 1.703(a)(6) is 179 days.

The total of the periods calculated in accordance with 37 CFR 1.703(a)(3) and (6) is 222 days.

Finally, even if the term lost due to delays prior to the Notice of Allowance is disregarded, it is respectfully submitted that the patent is still entitled to an adjustment of 179 days.

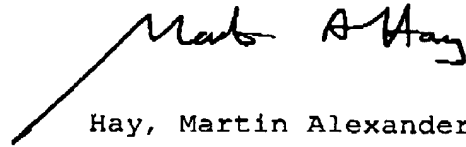
It is therefore respectfully submitted, in accordance with 37 CFR 1.703(f), that the term of the patent should be adjusted under 35 USC 154(b) by 274 days, by 222 days or at least by 179 days.

COMMUNICATION BY TELEPHONE

The undersigned's office is located in the United Kingdom, and hence the Examiner may have difficulty contacting him from the USPTO by telephone. If the Examiner wishes to speak with the undersigned by telephone, he can contact the undersigned by e-mail at martinahay@martin-a-hay.com, or leave a message with Linda McDonald at (317) 433 7140.

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Petition under 37 CFR 705(d)

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Martin A. Hay". The signature is written in a cursive style with a long, sweeping underline that extends to the left.

Hay, Martin Alexander
Agent for Applicants
Registration No. 39,459
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e-mail: martinahay@martin-a-hay.com

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June 2, 2005

** TX REPORT **

TRANSMISSION OK

TX/RX NO 2917
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ST. TIME 01/10 11:37
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Date: 1st October 2003 Total Number of Pages: 25
(including cover page)

To: Attn: Group Art Unit 1625
USPTO

FAX Number: +1 (703) 872 9306

From: Martin A Hay

FAX Number: (44) 1625 500058

Acknowledgment Requested: Yes No

Message:

US Appln Serial No. 10/030,189
Applicant: Liebeschuetz, et al
Our Ref: 00220/US

Response to Office Communication of July 1, 2003.

Martin A. Hay & Co.

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JUN 02 2005

Dr Thomas E Jackson
Patent Division
Eli Lilly and Company
P. O. Box 6288
Indianapolis
Indiana 46206-6288
UNITED STATES

23rd October 2003

Dear Tom,

Re: U.S. Patent Application Serial No. 10/030,189
Liebeschuetz, et al
Assigned to Eli Lilly and Company
Title: Serine Protease Inhibitors
Your Ref: X-14660/US
Our Ref: 00220/US

Please find enclosed a copy of the response that we faxed into the USPTO on October 1st, 2003. It has not yet been entered into PAIR, but I called the receptionist and she told me that the file has transferred to docketing on October 1st, 2003. We will keep a watch in PAIR.

Yours sincerely


Martin A Hay

Encl. Copies of papers submitted to USPTO

PAIR Page

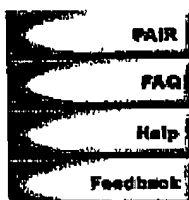
Page 1 of 1

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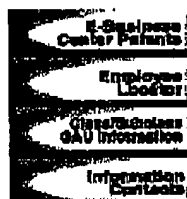


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PATENT APPLICATION INFORMATION RETRIEVAL6/11/03
closed

Other Links



Search results for application number:10/030,189			
Application Number:	10/030,189	Customer Number:	24330
Filing or 371(c) Date:	02-04-2002	Status:	Response to Non-Final Action Entered and For Examiner
Application Type:	Utility	Status Date:	11-05-2003
Examiner Name:	CHANG, CELIA C	Location:	TC 1800 LEGAL INST EXAMINER TEAM 4, C
Group Art Unit:	1825	Location Date:	11-05-2003
Confirmation Number:	8453	Earliest Publication No:	US 2003-0078438 A1
Attorney Docket Number:	00220/US	Earliest Publication Date:	04-24-2003
Class/ Sub-Class:	514/318	Patent Number:	-
First Named Inventor:	John Liebeschuetz, Bollington, (GB)	Issue Date of Patent:	-
Title Of Invention:	Serine protease inhibitors		

Continuity Data

Publication Review

Published Exam

File Contents History

Number	Date	Contents Description
16	11-05-2003	Date Forwarded to Examiner
15	10-01-2003	Response after Non-Final Action
14	06-23-2003	Information Disclosure Statement (IDS) Filed
13	07-01-2003	Mail Non-Final Rejection
12	06-30-2003	Non-Final Rejection
11	06-18-2003	Information Disclosure Statement (IDS) Filed
10	04-22-2003	Date Forwarded to Examiner
9	04-17-2003	Response to Election / Restriction Filed
8	03-19-2003	Mail Restriction Requirement
7	03-19-2003	Requirement for Restriction / Election
6	10-17-2002	Case Docketed to Examiner in GAU
5	09-17-2002	Transfer Inquiry to GAU
4	06-20-2002	Application Dispatched from OIPE
3	06-19-2002	IFW Scan & PACR Auto Security Review
2	06-04-2002	Notice of DO/EO Acceptance Mailed
1	02-04-2002	Initial Exam Team nn

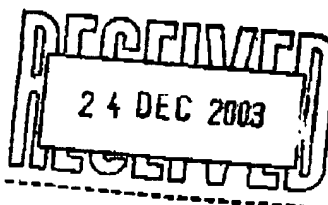
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,189	02/04/2002	John Walter Liebeschuetz	00220/US	8453
24330	7590	12/10/2003		
Martin A. Hay 13 Queen Victoria Street Macclesfield Cheshire UK, SK11 6LP UNITED KINGDOM				
			EXAMINER CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	10



DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Diary 21/04/04
 Scan 24/12/03
 Copy 16/10/04